UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 29, 2009

MEMORANDUM

Subject: Efficacy Review for Perasan C-5, EPA File Symbol 63838-RG; DP Barcode: D367558.

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Team Leader
Product Science Branch
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11/3/09

To: Karen Leavy / Marshall Swindell
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Enviro Tech Chemical Services, Inc.
500 Winmoore Way
Modesto, CA 95358

Formulation from the Label:

Active Ingredient	% by wt.
Peroxyacetic Acid	5.1 %
Hydrogen Peroxide	22.4 %
Other Ingredient (s):	72.6 %
Total	100.0 %

I. BACKGROUND

The product, Perasan C-5 (EPA Reg. No. 63838-RG), is a new product. The product is intended for use on food, dairy and beverage processing equipment, tanks, vats, pails, pipelines and closed systems. The product is intended for use on hard, non-porous surfaces. The applicant claims that the new product, Perasan C-5, is effective as a food-contact sanitizing rinse against *Staphylococcus aureus*, and *Escherichia coli.* Studies were conducted at Gibraltar Laboratories, Inc. located at 16 Montesano Road, Fairfield, NJ 07004.

The data package contained a cover letter, (dated June 25th, 2009), three studies (MRID 477968-03 through 477968-05), Statements of No Data Confidentiality Claims for all three studies, and the proposed label.

II. USE DIRECTIONS

The product is designed for sanitizing hard, non-porous food-contact surfaces such as tanks, vats, pails, pipelines and closed systems associated with dairy, food and beverage processing equipment. The label indicates that the product is highly acidic and should not be used around chlorinated product. The label also indicates that the product is safe on stainless steel and plastic, but should not be used on surfaces that contain copper, cast iron or mild steel, as severe corrosion will result. Directions on the proposed label provided the following information regarding preparation and use of the product as a sanitizer on hard, non-porous, food contact surfaces: Remove gross food particles and soil by a pre-flush or pre-scrape, when necessary. Clean all surfaces with an appropriate cleaning product, followed by a potable water rinse prior to application of the product. Sanitize CIP or COP equipment by immersion, circulation or coarse spray sanitizing techniques. Sanitize with a concentration of 1.0-2.3oz Perasan C-5 diluted in 5 gallons of water. Drain any excess solution. Do not rinse with potable water.

For non food contact hard surface disinfection against *Staphylococcus aureus* and *Salmonella enterica*, dilute 2.3-20oz in 5gallons of water. Allow to remain wet for 10 minutes. Surfaces that may directly or indirectly contact food must be rinsed with potable water before operations resume.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria): The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538). To support products labeled as "general disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Sanitizers (For Food Contact Surfaces): The effectiveness of sanitizers for food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. Testing requirements in EPA DIS/TSS-4 may be used. The test surface(s) should represent the type(s) of surfaces recommended for treatment

on the label, i.e., porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) or *Salmonella typhi* (ATCC 6539) or *Staphylococcus aureus* and *Escherichia coli* (ATCC 6538 and 11229). Acceptable results must show a bacterial reduction of at least 99.999 percent in the number of microorganisms.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 477968-03 "EPA Food Contact Sanitizer Test for Previously Cleaned Food-Contact Surfaces (AOAC Germicidal and Detergent Sanitizing Action of Disinfectants" for the product Perasan C-5. Test Organisms: *Staphylococcus aureus*, and *Escherichia coli*, by Daniel L. Prince. Study conducted at Gibraltar Laboratories. Study completion date – January 23, 2009. Laboratory Project Number: GR 2556.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), and *Escherichia coli* (ATCC 11229). Three lots (Lot Nos. Lot Nos. 843-8-1003-1, 843-8-1203-1and 843-8-1203-2) of the product, Perasan C-5, were tested according to AOAC Official Method 960.09 "Germicidal and Detergent Sanitizing Action of Disinfectants" (AOAC 18th Edition Chapter 6.3.03). Lot no. 843-8-1003-10 was at least 60 days old. *Staphylococcus aureus* and *Escherichia coli* were prepared according to the AOAC 18th Edition. One (1) mL of test substance was added to 639 mL of 200 ppm AOAC hard water (volume to volume). Use dilution was prepared using 99 mL of water containing the product tested at the concentration to be tested, and was placed into 250 mL Erlenmeyer flasks. The use dilution was kept at a constant temperature bath until it reached 25±0.2°C, for at least 20 minutes. Duplicate flasks were prepared for each substance tested. Similar flasks were prepared for the controls. One (1) mL of culture suspension was added to each test flask. The suspension was added via pipette slightly immersed in the test solution. One (1) mL portions of the exposed culture were added to neutralizer exactly 30 and 60 seconds after the addition of the suspension and mixed well immediately after transfer. One (1) mL of exposed culture was transferred into 9 mL of neutralizer broth and vortexed to dislodge adhering organisms. One mL and 0.1 mL were plated in quadruplicate and poured with Tryptone Glucose Extract Agar (TGEA). Plates were incubated for 48 hours at 37±1°C. The colony forming units were counted using a Quebec colony counter. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, sterility, neutralization system toxicity, and neutralizer effectiveness.

2. MRID 477968-04 "EPA Food Contact Sanitizer Test for Previously Cleaned Food-Contact Surfaces (AOAC Germicidal and Detergent Sanitizing Action of

Disinfectants" for the product Perasan C-5. Test Organisms: *Salmonella enterica*, and *Listeria monocytogenes*, by Daniel L. Prince. Study conducted at Gibraltar Laboratories. Study completion date – February 23, 2009. Laboratory Project Number: GR 2558.

This study was conducted against *Salmonella enterica*, (ATCC 10708), and *Listeria monocytogenes* (ATCC 984). Two lots (Lot Nos. 843-8-1003-1 and 843-8-1203-1) of the product, Perasan C-5, were tested according to AOAC Official Method 960.09 "Germicidal and Detergent Sanitizing Action of Disinfectants" (AOAC 18th Edition Chapter 6.3.03). One (1) mL of test substance was added to 639 mL of 200 ppm AOAC hard water (volume to volume). Use dilution was prepared using 99 mL of water containing the product tested at the concentration to be tested, and was placed into 250 mL Erlenmeyer flasks. The use dilution was kept at a constant temperature bath until it reached 25±0.2°C, for at least 20 minutes. Duplicate flasks were prepared for each substance tested. Similar flasks were prepared for the controls. One (1) mL of culture suspension was added to each test flask. The suspension was added via pipette slightly immersed in the test solution. One (1) mL portions of the exposed culture were added to neutralizer exactly 30 and 60 seconds after the addition of the suspension and mixed well immediately after transfer. One (1) mL of exposed culture was transferred into 9 mL of neutralizer broth and vortexed to dislodge adhering organisms. One mL and 0.1 mL were plated in quadruplicate and poured with Tryptone Glucose Extract Agar (TGEA) (*S. enterica*) and poured with Brain Heart Infusion Agar (BHIA) (*L. monocytogenes*). Plates were incubated for 48 hours at 37±1°C. The colony forming units were counted using a Quebec colony counter. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, sterility, neutralization system toxicity, and neutralizer effectiveness.

3. MRID 477968-04 "AOAC 18th Edition Broad Spectrum Use-Dilution Test on "Perasan C-5"". Test Organisms: *Salmonella enterica*, and *Listeria monocytogenes*, by Jozef Mastej. Study conducted at Gibraltar Laboratories. Study completion date – April 01, 2009. Laboratory Project Number: GR 2567.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708). Three batches (Lot Nos. Lot Nos. 843-8-1003-1, 843-8-1203-1and 843-8-1203-2) of a product, Perasan C-5, were tested using the AOAC Use-Dilution Method 955.15 and 955.14, as described in the AOAC Official Methods of Analysis, 18th Edition. Lot no. 843-8-1003-10 was at least 60 days old at the time of testing. A use solution was prepared by adding 3.0 ml of product to 795.0 ml of 400 ppm AOAC hard water (volume to volume) or 5 ml of product to 1325 ml of 400 ppm AOAC hard water (volume to volume). Sixty (60) stainless steel penicylinder carriers per product lot and per organism were immersed for 15 minutes in a 48 hours old suspension of the test organisms containing 5% organic soil load (Bovine Calf Serum). The carriers were dried at 35-37°C for 40 minutes, and then exposed to 10 ml of the use solution for 10 minutes at 20±1°C. Following exposure, the carriers were transferred to AOAC Letheen Broth containing catalase. All tubes were incubated for 48±2 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included neutralization, viability control, carrier counts, purity, and sterility. The reported average colony forming units per carrier, for each test microorganism, are as follows: ***Salmonella enterica* 3.03 x 10^5 and *Staphylococcus aureus* 5.57 x 10^5**.

V. RESULTS

MRID Number	Organism	Test Substance/ Lot #	Results of 30 seconds contact time			
			Average Number Surviving (cfu/mL)	Microbes Initially Present (Log_{10})	Microbes Log_{10} Reduction	Percent Reduction
477968-03	*Staphylococcus aureus*	843-8-1003-1	<10	7.95	≥6.95	>99.999%
		843-8-1203-1	<10	7.95	≥6.95	>99.999%
		843-8-1203-2	<10	7.95	≥6.95	>99.999%
	Escherichia coli	843-8-1003-1	<10	8.04	≥7.04	>99.999%
		843-8-1203-1	<10	8.04	≥7.04	>99.999%
		843-8-1203-2	<10	8.04	≥7.04	>99.999%
477968-04	*Salmonella enterica*	843-8-1003-1	<10	7.90	≥6.90	>99.999%
		843-8-1203-1	<10	7.90	≥6.90	>99.999%
	Listeria monocytogenes	843-8-1003-1	<10	7.99	≥6.99	>99.999%
		843-8-1203-1	<10	7.99	≥6.99	>99.999%

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Counts (CFU/ Carrier)
		Lot No. 843-8-1003-1	Lot No. 843-8-1203-1	Lot No. 843-8-1203-2	
477968-05	*Staphylococcus aureus*	0/60	0/60	0/60	5.57×10^5
	Salmonella enterica	0/60	0/60	0/60	3.03×10^5

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 477968-05) **support** the use of a **3:798** or **1:266** use solution of the product, Perasan C-5, as a disinfectant with bactericidal activity against *Staphylococcus aureus* and *Salmonella enterica*, on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a 10-minute contact time. Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. At least one of the product lots tested was at least 60 days old at the time of testing. Neutralizer effectiveness testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data (MRID 477968-03 and MRID 477968-04) **support** the use of the product, Perasan C-5, when diluted 640 times, as a food contact sanitizer against the following microorganisms on hard, non-porous, surfaces in the presence of **200 ppm** AOAC hard water for a contact time of 30 seconds:

Staphylococcus aureus (ATCC 6538)
Escherichia coli (ATCC 11229)
Salmonella enterica, (ATCC 10708)
Listeria monocytogenes (ATCC 984)

A bacterial reduction of at least 99.999 percent over the parallel control within 30 seconds was observed. Neutralization confirmation testing showed positive growth of the microorganisms. Sterility controls did not show growth.

VII LABEL

1. The proposed label claims that the product, Perasan C-5, when diluted 640 times (**1oz/5gal**), is an effective food contact sanitizer against the following microorganisms on pre-cleaned, hard, non-porous surfaces with a contact time of 60 seconds:

Staphylococcus aureus (ATCC 6538)
Escherichia coli (ATCC 11229)
Salmonella enterica, (ATCC 10708)
Listeria monocytogenes (ATCC 984)

Data provided by the applicant **support** these claims.

2. The proposed label claims that the product, Perasan C-5, is an effective disinfectant against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708), when used at 2.3oz/5gal with up to 400 ppm $CaCO_3$, in the presence of 5% organic soil, for 10 minutes contact time **are not acceptable until the registrant change the dilution rate to 2.41-20 oz/5gal or 2.5-20 fl oz/5gal**. 2.3oz/5gal dilution is higher than the tested dilution of 1:266.

3. ATCC designation numbers are required in one of the following locations:

- on the data matrix;
- on the master label (as optional text) with the listing of the organisms claimed; or
- As the final page of the master label (as optional text).

4. The applicant must make the following changes to the proposed label, as appropriate:

- On page 1 of the proposed label, under "Directions for Use" and under Sanitization change "....when solution is prepared in water up to **400 ppm** hardness of $CaCO_3$." to read "....when solution is prepared in water up to **200 ppm** hardness of $CaCO_3$."